REMARKS

For the Examiner's convenience, Applicants will now address stated issued and grounds for rejection of the pending claims under the appropriate subheadings.

Rejection of Claims 2-3 and 8-15 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 2-3 and 8-15 under 35 U.S.C. § 103(a) as being unpatentable over Keim (U.S. Patent No. 3,700,623) in view of McTaggart (U.S. Patent No. 5,462,730). In particular, the Examiner stated that although Keim does not teach that the described resins can be used in a pharmaceutical composition, one of skill in the art would recognize the resins as suitable for a pharmaceutical composition because McTaggart demonstrates that polyallylamine polymers can be formulated as such. Applicants disagree with the Examiner's assertions.

Applicants' Invention

Applicants' claims are directed to a pharmaceutical composition comprising a unit dosage form of a polydiallyamine homopolymer, which is free of alklylated amine monomers, and a pharmaceutically acceptable carrier. Each of the two independent claims specify the structure of the unit dosage form (i.e., Claim 2 specifies a tablet and Claim 8 specifies a capsule).

Non-Analogous Art

As a preliminary matter, Keim is non-analogous art and the reference is therefore improperly relied upon by the Examiner in rejecting Applicants' claims. More specifically, references within the statutory terms of 35 U.S.C. §102 qualify as prior art for an obviousness determination only when analogous to the claimed invention. *In re Clay*, 966 F.2d, 656, 658 (Fed. Cir. 1992). Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). Keim fails both tests.

In the present application, the claimed invention is in the field of pharmaceuticals, whereas Keim is in the field of paper processing. The Examiner asserted that one of ordinary skill in the art would recognize Keim's resin as suitable for pharmaceutical formulation. On the contrary, pharmaceuticals and paper processing are easily recognized as two different fields of endeavor. That Keim and the present invention are in different technical fields is evidenced by the fact that Keim has an international classification of C08f, whereas the present invention has an international classification of A61K (see e.g., the cover pages of U.S. Patent Nos. 6,083,497, 6,264,938 and 6,248,318, over which the present application has been disclaimed). As such, one or ordinary skill in the art of pharmaceuticals would not look to the paper processing art to prepare pharmaceutical compositions or conversely, because the fields are vastly different.

Furthermore, the teachings of Keim are not reasonably pertinent to the particular problem with which the inventors were involved. The purpose of Keim is to process paper with superior wet and dry strengths, not to provide a pharmaceutical composition in unit dosage form for treatment of, for example, hypercholesterolemia. One of ordinary skill in the art would not look to the field of paper processing, to solve a problem in the field of pharmaceuticals. As such, Keim is non-analogous art and therefore an improper reference.

Deficiencies of Kiem

Keim teaches water soluble resins that are used as wet strength agents for paper and that also provide dry strength to paper. At Col 3. lines 63-75, Keim teaches that the aqueous resins are applied to the paper by tub application or by spraying of an aqueous resin solution having a solids content of 15% or less. Alternatively, this aqueous solution of resin can be added to an aqueous suspension of paper stock before paper sheet formation. There is no teaching or suggestion in Keim that the water soluble resin materials used to provide a paper with superior wet and dry strengths (e.g., wrapping paper), be used to prepare a pharmaceutical composition in a solid form, nevermind as solid unit dosage form pharmaceutical.

More specifically, the aqueous resin solution of Keim would not motivate one of ordinary skill in the art to prepare a pharmaceutical composition in the unit dosage form of a tablet or a capsule. In fact, preparation of a solid unit dosage form would be contrary to the teachings of Keim, which require an aqueous resin solution to strengthen paper. In other words, one of

ordinary skill in the art would not be motivated to substitute a capsule or tablet for the aqueous resin solution of Keim, because such a form would destroy the ability to apply the resin to paper, because one cannot spray a tablet or capsule onto paper or dip paper in a tablet. Furthermore, the use of the resin prior to paper formation requires the addition of the aqueous resin solution, not a tablet or capsule, to the paper stock suspension. Finally, Claims 14 and 15,which recite that the polymer is water-insoluble, are even more distinct from the teachings of Keim, which require that the resin is water-soluble.

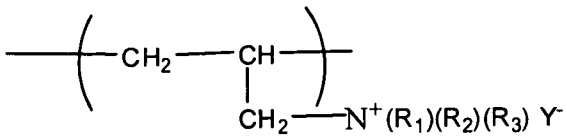
The Examiner reminded Applicants that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In response, Applicants point out that the deficiencies of Kiem, as discussed in detail above, go far beyond not teaching a pharmaceutical composition as stated by the Examiner. As such, individual discussion of Keim is necessary in order to fully appreciate the deficiencies of Kiem (i.e., paper processing not pharmaceutical development; polymer solutions not solid polymers; and no pharmaceutical compositions). The combination of Kiem and the secondary reference, McTaggart, is fully addressed below.

The Examiner relies on McTaggart to cure the deficiencies of Keim. Applicants submit that the teachings of McTaggart do not cure the deficiencies of Kiem because:

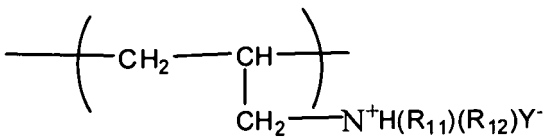
- the polymers of McTaggart are structurally diverse from the polymers of Kiem; and
- the polymers of McTaggart are water-insoluble, while Kiem's polymers are water-soluble.

Structural Diversity

The polymers of McTaggart are insoluble swellable polymeric allylammonium derivatives having a quaternary propylammonium monomeric unit of the following formula:

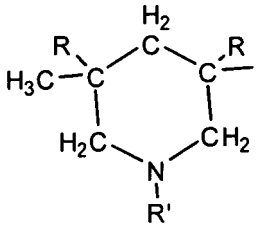


a crosslinking unit and a propylamine unit of the formula:



where the R groups can be alkyl or phenyl moieties.

On the contrary, the polydiallylamine polymers of Keim having the following cyclic monomer unit (McTaggart's monomer unit is non-cyclic) and no quaternary ammonium (required by McTaggart):



where R is hydrogen or alkyl and R' is hydrogen, alkyl or substituted alkyl.

Based on the significant structural diversity in the monomers unit of Keim and McTaggart, one of ordinary skill in the art would not be motivated to substitute the polydiallylamine of Keim for the propylammonium-containing polymer of McTaggart. More specifically, substitution of the propylammonium-containing polymer of McTaggart with the polydiallylamine polymer of Keim is not a routine substitution of one amine polymer for another to obtain predictable results, because of the significant structural diversity between the described polymers and the fact that Kiem provides paper processing as its sole use. Furthermore, McTaggart provides no suggestion or teaching that polymers other than the non-cyclic, hydrophobic propylammonium-containing polymers are suitable for use in the described pharmaceutical compositions. As such, one would not be motivated to use other amine polymers in the pharmaceutical compositions of McTaggart, and certainly not the structurally diverse amine polymers of Keim, useful for paper processing.

Water Solubility

Keim teaches that the described polydiallylamine polymers, used in paper processing, are water-soluble. On the contrary the polymers of McTaggart are water **in**soluble. Based on the

difference in this important physical characteristic of the polymers, one of ordinary skill in the art would not be motivated to substitute the polydiallylamine polymer of Keim for the propylammonium-containing polymer of McTaggart, with any reasonable expectation of obtaining a solid pharmaceutical composition as claimed by Applicants.

In view of the above, Applicants' claims meet the requirement of 35 U.S.C. 103(a) and are patentable over the teachings of Keim either alone or in combination with McTaggart. Reconsideration and withdrawal of the rejection are respectfully requested.

Finally, the Examiner's reference to *In re Spada* on page 5 of the Office Action is not understood. The pending rejection is based on obviousness of Applicants' claimed invention, not anticipation as the application of *In re Spada* would suggest. In any event, the aqueous solution of water soluble resin described in Keim is not identical to the unit dosage form (i.e., tablet or capsule) of Applicants' claimed invention, particularly the composition of Claims 14 and 15, which recite that the polymer is water-insoluble.

Applicants believe all pending claims meet the requirement of 35 U.S.C. 103(a) and are patentable over the teachings of Keim. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira

Susan M. Abelleira
Registration No. 42,252
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Date: October 02, 2008